DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103172/5009

MAY 15 2002

Robert L. Garnick, Ph.D.
Genentech, Incorporated
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Garnick:

Your request to supplement your biologics license application for Alteplase, to revise the package insert to include adding information regarding orolingual angioedema to the Precautions and Adverse Reactions sections, and bolding a statement in the Dosage and Administration section, has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research